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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,413	03/30/2001	Shigeru Yamamoto	Q63731	8678

7590 05/29/2003
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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/806,413

Applicant(s)

YAMAMOTO ET AL.

Examiner

David J. Steadman

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 4.

Claim(s) objected to: _____.

Claim(s) rejected: 1-3, 11-14 and 21.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15.

10. ☐ Other: _____

ADVISORY ACTION

[1] Status of the claims:

[a] Claims 1-4, 11-14, and 21 are pending in the application.

[b] Claims 1-3, 11-14, and 21 are rejected.

[c] Claim 4 is in a condition for allowance.

[2] The request for reconsideration in the after final amendment of Paper No. 17, filed May 09, 2003, is acknowledged. The amendment would appear to overcome the rejection under 35 USC 112, second paragraph, the new matter rejection under 35 USC 112, first paragraph, and the rejections under 35 USC 102(b) and 102(e) as described below. However, the amendment does not place the claims in condition for allowance because the amendment would require further consideration of the claims and a new search. See MPEP 714.13 regarding non-entry of after final amendments.

[3] The rejection of claims 1-3 and 11-14 under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record (see item 2a and 2b of Paper No. 14). Applicant argues (page 6, item I of Paper No. 17) the rejection has been overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the instant rejection.

[4] The new matter rejection of claims 1, 2, and 11-14 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (see item 3 of Paper No. 14). Applicant argues (pages 6-7, item IIA of Paper No. 17) the rejection has been overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the instant rejection.

[5] The written description rejection of claims 1-3 and 11-14 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (see item 4 of Paper No. 14). Applicant argues (pages 7-9, item IIB of Paper No. 17) the rejection has been overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would **not** appear to overcome the instant rejection. The following comments are directed to claims as

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presented in Paper No. 17. The written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. As stated in a previous Office action, the specification provides only two representative species of such isolated polypeptides, i.e., a mature diglycosidase having an amino acid sequence of SEQ ID NO:8 and an inactive precursor diglycosidase of SEQ ID NO:10 (SEQ ID NO:8 with an additional 22 amino acids at the N-terminus), both isolated from a single microorganism, *Aspergillus fumigatus*. While the claims recite the relevant identifying characteristics of the enzymatic activity, the substrate, pH range of activity, temperature stability range, and source, these characteristics fail to describe the genus of isolated enzymes such that one skilled in the art would reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

[6] The scope of enablement rejection of claims 1-3, 11-14, and 21 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (see item 5 of Paper No. 14). Applicant argues (pages 9-10, item IIC of Paper No. 17) the specification is enabling for the entire scope of the claimed invention and the rejection has been overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would **not** appear to overcome the instant rejection. The following comments are directed to claims as presented in Paper No. 17. The examiner maintains his position that undue experimentation would be required for a skilled artisan to make the entire scope of isolated polypeptides. Regarding claims 11, 13, and 14, while the specification indicates that primeverosidase activity is present in extracts of the recited microorganisms following a particular culture method, this is no indication that a skilled artisan, using other cell culture techniques, would obtain similar results. A skilled artisan would recognize that enzyme

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expression in a cultured microorganism is dependent upon numerous factors including culture medium composition and pH, temperature, time of culturing, etc. As applicants have provided guidance for only a single set of culture conditions that result in primeverosidase activity in the extracts of the recited strains of microorganisms, one of skill in the art would recognize the high degree of unpredictability that using other culture conditions would produce similar results. Regarding claims 1-3, 11, 13, and 14, applicant has demonstrated the isolation of only a single working example of the broad scope of isolated polypeptides encompassed by the claims, i.e., *Aspergillus fumigatus* beta-primeverosidase. A skilled artisan would recognize the unpredictability for isolating a first enzyme using conditions established for purification of a second homologous enzyme. The ability to purify or isolate an enzyme is dependent upon numerous factors including size (Stokes radius) of the desired polypeptide, the charge or pI of the enzyme, ligand binding activity, etc. There is no indication in the specification or the prior art that the beta-primeverosidase of the recited strains shares those characteristics with *Aspergillus fumigatus* beta-primeverosidase such that beta-primeverosidase of the recited strains can be isolated using the purification profile as established for *Aspergillus fumigatus* beta-primeverosidase. Also, it is noted that the claims recite genera of microorganisms, while beta-primeverosidase activity was shown to be present only in *species* of the recited genera. One of skill in the art would recognize that not all species of a genus of microorganism may express a particular enzyme. Regarding claim 3, there is no guidance in the specification for altering the sequence of SEQ ID NO:8 with an expectation of maintaining beta-primeverosidase activity along with those additional characteristics recited in the claim. Also, the effects of such alteration, including addition, deletion, insertion, and substitution would be highly unpredictable. Thus, in view of the broad scope of the claims, the lack of guidance and working examples presented in the specification, and the high degree of unpredictability, undue experimentation would be required to make the entire scope of the invention.

[7] The rejection of claims 1, 3, and 11-13 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McCormack et al. (*Biotechnol Lett* 13:677-682) is maintained for the reasons of record (see item 8 of Paper No. 14). Applicant argues (pages 10-11, item

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IIIA of Paper No. 17) the rejection is overcome by amendment as the chitobiase of McCormack et al. does not have the same enzymatic activity as recited in the claims. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the instant rejection.

[8] The rejection of claim 3 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Harman et al. (US Patent 6,020,540) is maintained for the reasons of record (see item 9 of Paper No. 14). Applicant argues (pages 11-12, item IIIB of Paper No. 17) the rejection has been overcome by amendment as the chitobiase of Harman et al. does not have the same enzymatic activity as recited in the claims. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the instant rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

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REBECCA E. PROUTY
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